UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,278	07/31/2001	Herm Snyder	0068.00	4703

21968 7590 01/04/2006

NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER	
YEBASSA, DESTA LETTA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,278	SNYDER ET AL.	
	Examiner	Art Unit	
	Desta L. Yebassa	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 18-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 18-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 01/20/2004 and 12/15/2003
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made for the information disclosure statement (IDS) filed on 01/20/2004 and 12/15/2003. Receipt is also acknowledged of the oath or declaration filed on 07.31/2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ketcham et al. (U.S. Patent No. 4,871,489) in view of Backstrom et al. (U.S. Patent No. 5,952,008), Forrester et al. (U.S. Patent No. 4,590,206).

Ketcham et al. teaches an apparatus and process for producing liquid droplets having a narrow size distribution, wherein this liquid streams are forced under pressure through a plurality of orifices in an orifice plate, wherein the thin liquid streams are

vibrated to cause the breakup of each stream into droplets having a narrow size distribution (abstract), a vibrating members and a separate plate comprising holes (column 2, lines 65, column 3, lines 5-20, and column 3, lines 55-65); Ketcham et al. also teaches that the mean orifice diameter is between from about I micron to about 10 microns, or between from about 2 microns to about 5 microns, and that the diameter of the larges orifice is not greater than about three times the diameter of the smallest orifice in the plate. The range of 2 to 5 microns clearly reads on Applicant's limitation that the particle size distribution is less than 4 microns (column 5-6). Furthermore, Ketcham teaches a processing step, after the formation of the droplets, wherein the droplets are processed into particles having a narrow size distribution and a mean number diameter of up to about 5 microns; this processing step may comprises entraiaing said droplets in an inert dilution gas, which provides a drying medium for removal of the liquid carrier medium by evaporation; and the processing step that may include steps such as cooling, freezing, heating, chemical reaction, and the like (column 8, lines 65 and column 9, lines 15-40).

Backstrom et al. disclose a pharmaceutical composition including a mixture of active compounds and a pharmaceutical active polypeptide, the mixture being in the form of a dry powder for inhalation in which the primary particles having a diameter less than or equal to about 10 microns (abstract); the pharmaceutical active agents of polypeptide selected from the group such as insulin, calcitonin, human growth hormone (HGH), growth hormone (GH), growth hormone releasing hormone (GHRH), luteinizing hormone releasing hormone (LHRH), C-peptide of insulin, parathyroid hormone (PTH),

vasopressin, glucagons, corticotrophin (ACTH), oxytocin, corticotrophin releasing hormone (CRH), somatostatin, follicle stimulating hormone (FSH), growth factors,interleukins, enzymes, etc. and a pharmaceutically acceptable carrier, which preparation is in the form of a dry powder suitable for inhalation (column 4, lines 20-30 and column 7, lines 55-65).

Forrester et al. disclose a method of making the fine particles of inhalation drugs e.g. sodium cromoglycate, comprising a therapeutically effective proportion of individual particles capable of penetrating deep in to the lung, characterized in that a bulk of the particles which is both unagglomerated and unmixed with a coarse, is sufficiently free flowing to be filled in to capsules on an automated filling machine and to empty from an opened capsule in an inhalation device, and these particles can disperse well from an inhaler at both low and high air flow rates (abstract and column 1, lines 65 and column 2, lines 5-30). Forrester et al. also disclose a spray drying apparatus preferably comprises the automiser, a main chamber, one or more cyclones, a bag filter, etc.; examples of suitable medicaments include those used for the inhalation treatment such as pharmaceutically acceptable salts; bronchodilators such as isoprenaline, salbutamol, etc antibiotics such as tetracycline, steroid etc. and the suitable medicaments used particularly preferred at least 50 % of the particles to be of 2-6 microns in diameter (column 4, lines 45-65 and column 6, lines 40-55).

The primary reference, Ketcham et al., teaches an apparatus and process for producing liquid droplets having a narrow size distribution, wherein this liquid streams are forced under pressure through a plurality of orifices in an orifice plate, wherein the

thin liquid streams are vibrated to cause the breakup of each stream into droplets having a narrow size distribution; a vibrating members and a separate plate comprising holes; the mean orifice diameters and the small and large orifice diameters; a processing step, after the formation of the droplets, wherein the droplets are processed into particles having a narrow size distribution; processing step that may include steps such as cooling, freezing, heating, chemical reaction, and the like. The primary reference, Ketcham et al., does not teach a pharmaceutically active agents such as insulin, calcitonin, human growth hormone (HGH), growth hormone (GH), growth hormone releasing hormone (GHRH), luteinizing hormone releasing hormone (LHRH), inhalation drugs and treatment such as pharmaceutically acceptable salts; bronchodilators such as isoprenaline etc.

However, the secondary references teach a pharmaceutically active agents including a mixture of active compounds and a pharmaceutical active polypeptide, the mixture being in the form of a dry powder for inhalation in which the primary particles having a diameter less than or equal to about 10 microns; the pharmaceutical active agents were selected from the group such as insulin, calcitonin, human growth hormone (HGH), growth hormone (GH), growth hormone releasing hormone (GHRH), luteinizing hormone releasing hormone (LHRH), C-peptide of insulin, parathyroid hormone (PTH), vasopressin, glucagons, corticotrophin (ACTH), oxytocin, corticotrophin releasing hormone (CRH), somatostatin, follicle stimulating hormone (FSH), growth factors, interleukins, enzymes, etc. and a pharmaceutically acceptable carrier, which preparation is in the form of a dry powder suitable for inhalation; a method of making

the fine particles of inhalation drugs e.g. sodium cromoglycate, comprising a therapeutically effective proportion of individual particles capable of penetrating deep in to the lung, characterized in that a bulk of the particles which is both unagglomerated and unmixed with a coarse, is sufficiently free flowing to be filled in to capsules on an automated filling machine and to empty from an opened capsule in an inhalation device, and these particles can disperse well from an inhaler at both low and high air flow rates; examples of suitable medicaments include those used for the inhalation treatment such as pharmaceutically acceptable salts; bronchodilators such as isoprenaline, salbutamol, etc antibiotics such as tetracycline, steroid etc. and the suitable medicaments used particularly preferred at least 50 % of the particles to be of 2-6 microns in diameter etc.

The prior art recited as combined teach all the limitations of the instant claims. The instant claims differ from the references only in the specific percentage and the size of diameter range selected for the particles. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to select any of the apparatus and process, pharmaceutical active agents such as insulin, calcitonin, human growth hormone (HGH), growth hormone (GH), growth hormone releasing hormone (GHRH), luteinizing hormone releasing hormone (LHRH), C-peptide of insulin, parathyroid hormone (PTH), vasopressin, glucagons, corticotrophin (ACTH), oxytocin, corticotrophin releasing hormone (CRH), somatostatin, follicle stimulating hormone (FSH), growth factors, interleukins, enzymes, etc. and a pharmaceutically acceptable carrier for forming a particles having a narrow size distribution, made from a feed stock, because the determination of a specific percentage and diameter range of a

particles having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa, PhD
Patent Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600